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| EXAMINER |
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YOUNG, MICAH PAUL

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| ART UNIT | PAPER NUMBER |
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1618

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| MAIL DATE | DELIVERY MODE |
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08/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/980,697 | Applicant(s) LUTHRA ET AL. | |
| | Examiner MICAH-PAUL YOUNG | Art Unit 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-65,67 and 68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-65,67 and 68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/27/08</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 5/27/08

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-65 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case the newly amended claims recite that the biguanide containing moiety comprises a plurality of biguanide groups, however the specification does not appear to support this amendment. Applicant points to an example directed to a polyhexidine methacrylate polymer however it does not appear to comprise a plurality of biguanide groups. No other examples in specification comprise a plurality of biguanide groups. Since neither the examples, nor any disclosures throughout the remaining specification provide a plurality of biguanide groups in the polymer chain it would be impossible for an artisan of ordinary skill in the art to make/use the invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 39-65 and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite that the polymeric material comprises a plurality of biguanide groups, however this "plurality" is not further defined or explained by the claims or specification. Are these plurality of biguanides all attached to the polymer chain the same way? Does the plurality mean several of the same biguanide or multiple and different biguanide compounds. Only two biguanide compounds are recited in the claims. The claim does not make clear how many of these compounds are present if at all. Is this "plurality" the same as found in the repeating units that define a polymer or is the plurality. This amendment is unclear to the Examiner and for the purposes of Examination the claims will be interpreted as meaning multiple biguanide compounds as found in a repeating polymer chain.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 39-65 and 67-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Spooner et al (WO 98/20738 hereafter '738) in view of Olstein 5,142,010 hereafter '010) and Solomon et al (USPN 5,451,424 hereafter '424). The claims are drawn to a polymeric material comprising an infection resistant biguanide containing a plurality of biguanide groups bound by some but not all of the secondary amine groups. The claims further recite a method of making the polymer.

The '738 patent discloses a disinfecting contact lens comprising bis(biguanides) providing enhanced antimicrobial efficacy (abstract). The bis(biguanide) can be combined with polymeric biguanide compounds. These bonds are through the secondary amine groups (Formula IV and V). These compounds include polyhexanide (Formula V). The polymers can be further blended with surfactants to form a coating or cleansing composition, where the surfactants include propylene glycol, polyethylene glycol and polyoxyethylene based surfactants (page 19, lin. 11-30). The reference is silent to the specific reactive sites of the polymer however the polymerization methods are well known in the art as seen in the '010 patent, which discloses various polymerization methods and compounds useful in processing polymeric biguanide compounds.

The '010 patent teaches a polymeric biguanide formulation where one of the nitrogen atoms is bonded by an amine linkage (col. 2, lin. 15-65). The polymer formed is infection resistant and is useful in bulk polymers and copolymers (col. 3, lin. 49-65). The polymeric material is incorporated into various forms useful in or on the human body and as a coating, or an implantable medical device (col. 4, lin. 54-65; col. 13, lin. 21-36). The reaction sites binding to

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the polymer include isocyanate (col. 2, lin. 56-60). The polymers are subsequently blended with other polymers such as acrylic acid derivatives and methacrylate derivatives (col. 9, lin. 50-65). The formation of the polymer requires a polymerization process (col. 10, lin. 51-68). The process includes the incorporation of a carbodiimide (Example III). The polymers are combined with polymers useful for ocular lenses such as silicones (col. 12, lin. 20-25). The reference is silent to the specific biguanide compound useful in making the biocidal polymers, however various biguanide compounds are well known to those of ordinary skill in the art. These compounds can be found in the '424 patent.

The '424 patent discloses a biguanide polymer comprising chlorhexidine (abstract). The biguanide is bound to polyurethane and used for medical tubing (example 1). Polyurethane is one of the many polymers used in grafting the biguanides of the '010 patent, therefore a skilled artisan would be motivated to include the biguanides of the '424 into the preparation of the '010.

The combination is silent to the tertiary amine groups being bound to a biguanide residue, however the combination of provides a biocidal polymer using the same compounds as the instant claims. Tertiary amino groups would be expected in charged biguanide compounds such as chlorhexidine or polyhexanide. Chlorhexidine is the biguanide used in the '424 patent. It would have been obvious to combine the specific biguanide compound of the '424 into the polymers of the '010 since each reference teaches similar polymeric structures and uses. The tertiary amine groups would be an inherent by product of the polymerization process. The '010 patent provides a method of making biocidal polymeric compounds comprising the combination of biguanide compounds with polymeric structures where the bonds occur at isocyanate reactive sites along the polymer chain, and carbodiimide coupling agents are used. According to the

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specification a partial free base must be formed when using chlorhexidine or polyhexanide, thus this step is also obviously be taken by one of ordinary skill in the art follow the teachings and suggestions of the prior art combination.

With these things in mind it would have been obvious to combine the teaching and suggestions of the art in order to provide a stable composition useful in treating a wide variety of bacterial infections. It would have been obvious to combine the process the bis(biguanide) of the '738 patent by the process of the '010 patent in order to provide a stable coating formulation. The patents share similar compounds and can be used in the ocular procedures. It would have been have been obvious to combine this compound with the '424 patent in order to arrive at a specific medical device. It would have been obvious to combine the teachings and suggestions with an expected result of an infection resistant polymer useful in ocular devices.

Response to Arguments

Applicant's arguments with respect to claims 39-65, 67 and 69 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618
/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618